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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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FISH & RICHARDSON PC			ARNOLD, ERNST V	
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MINNEAPOLIS, MN 55440-1022			PAPER NUMBER	

1616

DATE MAILED: 09/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/679,738

Applicant(s)

NOVIKOV ET AL.

Examiner

Ernst V. Arnold

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) 27-29 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) ☒ Notice of References Cited (PTO-892) | 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) ☐ Notice of Informal Patent Application (PTO-152) |
| 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>10/07/04, 03/17/05</u> . | 6) ☐ Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- Group I. Claims 1-26 are drawn to a moisturizing composition, classified in class 424, subclass 401.
- Group II. Claims 27-29 are drawn to a method of making a moisturizing composition comprising combining an aqueous phase and lipid phase to form an emulsion, classified in class 514, subclass 937.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the composition of the Group I invention can be prepared by purchase of commercially available multi-bilayered microvesicles and mixing the appropriate ingredients.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

A telephone call was made to Celia Leber on 07/25/05 to request an oral election to the above restriction requirement and Group 1 claims 1-26 were elected. Claims 27-29 are withdrawn from examination as being drawn to non-elected subject matter. Accordingly, claims 1-26 are presented for examination on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2, 19 and 26 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The word "active" can be interpreted as an adjective meaning 'characterized or accomplished by action or effort' or 'engaged or participating in action or activity'. The word "active" is generally used in grammar to indicate that the subject of the sentence is performing or causing the action expressed by the verb. In this case, it is unclear to the Examiner what is being "active" in this sentence. It would be clearer if the word "component" were inserted after the word active.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 1-6, 8, 11-14, 17-20 and 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Mathur et al. (U.S. Patent No. 5,439,967).

Instant claim 1 is drawn to a moisturizing composition comprising: 60%-90% water, and as a moisturizing active, a plurality of bilayered microvesicles; wherein the bilayered microvesicles comprise an ethoxylated polyol ester of a fatty acid, a sterol, and a long chain fatty alcohol.

Mathur et al. claim a lipid vesicle containing a blend of amphiphiles in the lipid bilayer that are particularly useful for delivering dermatological, cosmetic and pharmaceutical formulations (Abstract). Mathur et al. claim a paucilamellar lipid vesicle having 2-10 bilayers (instant claim 5) comprising a mixture of propylene glycol stearate and at least one other amphiphilic selected from the group consisting of stearyl alcohol, polyoxyethylene fatty alcohols, polyoxyethylene derivatives of sorbitan fatty acid esters having 10-20 oxyethylene groups (Claims 1-4). Mathur et al. further anticipate the addition of at least one sterol, such as cholesterol, and a water immiscible material, such as soybean oil or vitamins (skin care active components) or avocado oil (claims 5-8).

Table 3 contains four examples of different compositions (Column 6, lines 43-52). Composition B is comprised of 66.9% water, 19.9% soybean oil, 3.5% cholesterol (a sterol), 0.99% polysorbate 60 (polyoxyethylene sorbitan monostearate; a water soluble polyethoxylated polyol ester of a fatty acid), 1.4% stearyl alcohol (a long chain, $\text{CH}_3(\text{CH}_2)_{16}\text{CH}_2\text{OH}$, fatty alcohol) and 7.1% propylene glycol stearate (a co-emulsifier). This composition meets the limitations of instant claims 1, 11-14. Soybean oil, a

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vegetable oil (instant claim 23) that is a source of vitamin E, contains 88% neutral lipids, 10% phospholipids and 2% glycolipids. Therefore, this composition would contain 1.9% phospholipids and meet the limitations of instant claims 6, 17, 18 and 24. Phospholipids are known emollients, which the Examiner interprets to be a skin care active component, thus meeting the limitations of instant claims 2, 4, 19 and 22. Soybean oil is a known source of vitamin E, which the Examiner interprets as a skin care active component, and reading on instant claims 2, 3, 19 and 20. Mathur et al. state that the average diameter of the vesicles was 549 nm thus meeting the limitation of instant claim 8. (Column 7, lines 5-6). The polysorbate 60 is a known water-soluble viscosity-modifying agent thus reading on instant claim 25.

Mathur et al. anticipate different polyoxyethylene derivatives of the fatty acid ester having 10-20 oxyethylene groups and the fatty acid ester can be derived from lauric acid $\text{CH}_3(\text{CH}_2)_{10}\text{COOH}$ (Column 2, lines 60-68). This reads on instant claims 9 and 15.

The reference of Mathur et al. is deemed to meet the limitations of instant claims 1-6, 8, 9 11-15, 17-20 and 22-25.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 16 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mathur et al.

The reference of Mathur et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Mathur et al. do not expressly disclose the ratio of ethoxylated polyol ester of a fatty acid, to sterol, to long chain fatty alcohol is in the range of about 1:0.2-0.5:1-2.

Mathur et al. disclose in Table 4 a ratio of polysorbate 60 to phytosterol to stearyl alcohol of 1:2.1:1.4 based upon about 0.3 grams of phytosterol in each gram of avocado oil (Column 7, lines 36-50). In this case, the avocado oil represents about 40% of the lipids. Mathur et al. state that the preferred range of avocado oil is 20-60% by weight of lipids thus suggesting to one of ordinary skill in the art that less avocado oil can be used in the composition (Column 8, lines 11-14). It would have been obvious to one of ordinary skill in the art to adjust the ratio of avocado oil and hence the sterol content of the composition and produce the instant invention. Therefore, it is deemed merely a matter of routine optimization by one of ordinary skill in the art to adjust the amount of avocado oil in the composition to produce a mixture in the ratio of about 1:0.2-0.5:1-2 or the slightly narrower range of 1:0.3-0.4:1.2-1.7.

One of ordinary skill in the art would have been motivated to do this because lowering the amount of avocado oil would have resulted in a cost saving feature for the composition.

From the teaching of the reference, one of ordinary skill in the art would have had a reasonable expectation of success. Therefore, the claimed invention, as a whole,

would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited reference.

Claim Rejections - 35 USC § 103

Claims 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathur et al. in view of Patel, et al. (U.S. Patent No. 6,309,663).

The reference of Mathur et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Mathur et al. do not expressly disclose a composition comprised of PEG-20 glyceryl laurate.

Patel et al. disclose an absorption-enhancing carrier comprised of at least two surfactants for the delivery of therapeutic agents (See: Abstract; Column 4, lines 45-67; and Column 5, lines 1-20, for example). Patel et al. disclose that a variety of PEG-fatty acid esters have useful surfactant properties (Column 6, lines 58-59) as well as PEG-glycerol fatty acid esters (Column 9, lines 47-53). A preferred hydrophilic surfactant is PEG-20 glyceryl laurate.

It would have been obvious to one of ordinary skill in the art at the time the claimed invention was made to modify the composition of Mathur et al. with PEG-20 glyceryl laurate as suggested by Patel et al. to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because PEG-20 glyceryl laurate is commercially available and routinely used in the preparation of emulsions and is a preferred surfactant as stated by Patel et al.

From the teaching of the references, one of ordinary skill in the art would have had a reasonable expectation of success. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Claim Rejections - 35 USC § 103

Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mathur et al. in view of Schonrock et al. (U.S. Patent No. 6,296,857).

The reference of Mathur et al. is discussed in detail above and that discussion is hereby incorporated by reference.

Mathur et al. do not expressly disclose the addition of sunscreen components to their composition.

Schonrock et al. disclose that high quality cosmetic compositions are unthinkable without the customary adjuvants and additives including sunscreens (Column 10, lines 65-67 and Column 11, lines 1-5). Schonrock et al. point out the oxides of zinc and titanium as suitable inorganic pigments to protect the skin from UV rays (Column 12, lines 29-37).

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It would have been obvious to one of ordinary skill in the art to modify the composition of Mathur et al. with a sunscreen component as suggested by Schonrock et al. to produce the instant invention.

One of ordinary skill in the art would have been motivated to do this because Schonrock et al. state that it is a common practice in this art to mix adjuvants and additives in with cosmetic preparations.

From the teaching of the references, one of ordinary skill in the art would have had a reasonable expectation of success. Therefore, the claimed invention, as a whole, would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention and the claimed invention as a whole have been fairly disclosed or suggested by the teachings of the cited references.

Conclusion

Claims 1-26 are rejected.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ernst V. Arnold whose telephone number is 571-272-8509. The examiner can normally be reached on M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

EVA


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